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10/702,236	11/05/2003	Donald Hetzel	SENS0002	7940

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/702,236	HETZEL ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 4/3/2008, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have cancelled claims 1-6, 8-16, 21-26, 28-30, 32, and 33 in their response filed 4/3/2008, which has been acknowledged and entered.

Upon further consideration prosecution will be re-opened with the issuing of the instant Non-Final Office action addressing the issues of claim 17.

Claim 17 is the current claim hereby under examination.

Previously Pending Claims and Rejections of those claims

It is noted on the record that applicant has cancelled all the previously rejected claims and therefore the rejections in the Final Office action mailed out 12/13/2007 addressing the now cancelled claims are being withdrawn because of applicant's cancellation of said claims.

The following rejections are being newly made:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Hockersmith et al. (US A/N 2004/0197846).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 17 is drawn to a method for screening a subject for disorders of glucose metabolism, comprising measuring a glucose concentration profile, said glucose concentration profile comprising a plurality of blood glucose concentrations from at least after a glucose or meal challenge; generating a screening factor, wherein said screening factor comprises a mathematical representation of at least a plurality of glucose concentrations within said glucose concentration profile, wherein said screening factor is uniquely associated with a state of glucose metabolism disorder and classifying the subject into one of said states of glucose metabolism disorder based on evaluation of said screening factor, wherein said screening factor comprises an abstract representation of said glucose profile wherein said step of generating a screening factor comprises the step of calculating a weighted average of weighted parameters wherein

the parameters comprise a first parameter of glucose concentration, a second parameter comprising the rate at which glucose concentration rises, a third parameter comprising maximum monitored glucose concentration, a fourth parameter comprising duration that glucose remains elevated, a fifth parameter comprising the rate of decrease of glucose concentration after a peak, and a sixth parameter comprising the minimum glucose concentration after a maximum.

Hockersmith et al. teaches the parameters of claim 17 at Figure 2 and the equation at paragraph [0047]. Hockersmith et al. teaches the rest of the steps of claim 17 at paragraphs [0019] – [0039].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalatz et al. (US P/N 6925393) in view of Wyman (1966) and as evidenced by Wikipedia.

Claim 17 is drawn to a method for screening a subject for disorders of glucose metabolism, comprising measuring a glucose concentration profile, said glucose concentration profile comprising a plurality of blood glucose concentrations from at least after a glucose or meal challenge; generating a screening factor, wherein said screening factor comprises a mathematical representation of at least a plurality of

glucose concentrations within said glucose concentration profile, wherein said screening factor is uniquely associated with a state of glucose metabolism disorder and classifying the subject into one of said states of glucose metabolism disorder based on evaluation of said screening factor, wherein said screening factor comprises an abstract representation of said glucose profile wherein said step of generating a screening factor comprises the step of calculating a weighted average of weighted parameters wherein the parameters comprise a first parameter of glucose concentration, a second parameter comprising the rate at which glucose concentration rises, a third parameter comprising maximum monitored glucose concentration, a fourth parameter comprising duration that glucose remains elevated, a fifth parameter comprising the rate of decrease of glucose concentration after a peak, and a sixth parameter comprising the minimum glucose concentration after a maximum.

Kalatz et al. in the Abstract teaches measuring a glucose profile, which comprises a time series and evaluating the profile according to at least one profile. Kalatz et al. further teaches at Fig. 3, generating a curve for representing a plurality of glucose concentrations, which reads on a mathematical representation of at least a plurality of glucose concentrations within said glucose concentration profile. Additionally, the graph can be used as a screening factor for determining the state of the patient during the analysis, which reads on a screening factor comprising of a representation of a shape of said glucose concentration profile. Kalatz et al. in the abstract describes patients who have a chronic stat of glucose metabolism disorder such as diabetes mellitus and that the invention is to classify those patients based on

their blood glucose levels and meals consumed. Kalatz et al. at col. 7, lines 65-67, col. 8, lines 1-8 and col. 9 teaches that a screening factor is used to determine the state of the subject, which may be a hypoglycemic or hyperglycemic state, which reads on classifying a subject into a pre-diabetic condition of diabetes mellitus.

Kalatz et al. teaches four out of six parameters used in the equation of the instant method for determining a screening factor as follows. Kalatz et al. at column 2, lines 30-33 teaches determining the actual glucose concentration at a specific point in time, which reads on a first parameter comprising a glucose concentration. Kalatz et al. teaches at col. 6, lines 2-6 and lines 30-34 the calculation of the glucose flooding, which reads on the second parameter, which is the rate at which glucose concentration rises. Kalatz et al. at col. 7, lines 1-5 teaches the parameter of determining the duration that glucose remains elevated, which reads on the fourth parameter which comprises the duration that glucose remains elevated. Kalatz et al. at col. 7, lines 1-5 also teaches the fifth parameter comprising the rate of decrease of glucose concentration after a peak.

Kalatz et al. does not specifically teach parameter 3 and parameter 6, which are maximum monitored glucose concentration and minimum glucose concentration after a maximum.

However, the invention's function, as taught by Kalatz et al., is to keep a patient's glucose level within a pre-determined "normal" range of values. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that while monitoring glucose concentrations over time of a patient, that the maximum and minimum values of glucose concentrations would be two parameters that would be

routinely monitored by one of ordinary skill in the art and would not be an unpredictable or unobvious parameter to monitor. The two extreme parameters would inform the person of ordinary skill in the art of the extreme boundaries with which they are working within in order to try and maintain the glucose levels within "normal range."

Kalatz et al. does not specifically teach a method of generating a screening factor comprising the step of calculating a weighted average of weighted parameters according to the recited equation comprising the six parameters.

However, Kalatz et al. does teach at col. 7, lines 60-64 calculating a parameter measuring an increase glucose concentration as being effected by a weighting factor.

Wyman teaches at page 2205, left column, equation 3.3, calculating a total binding constant of a protein, which is a weighted average, by summing the binding factor of each residue multiplied by that residue's weighting factor and dividing by the sum of the weighting factors.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to add up each of the parameters comprising a glucose profile and linearly combine them with their effected weight factors and divide it by the sum of the weight factors, as taught by Wyman with respect to calculating a protein binding. One of ordinary skill in the art would find it routine to linearly combine all the parts that constitute an overall total value. As discussed above, each of the parameters comprising the glucose profile are well known and have been taught in the prior art. The mathematical step of linearly combining all the parts that constitute an overall total value is routinely performed by those of ordinary skill in the art. As Wyman teaches, it

is also routine in the art to understand that each of the parts comprising the total value contribute different amounts to the total, which is represented by using weighting factors. It is also well known and routine in the art to normalize data or divide by the sum of the weight factors to arrive at a weighted average as taught by Wyman. Furthermore, Wikipedia teaches that the general formula for calculating a weighted mean is well known and routinely used in the art as defined by the following:

Weighted mean

From Wikipedia, the free encyclopedia

The **weighted mean**, or **weighted average**, of a non-empty set of data

$$[x_1, x_2, \ldots, x_n],$$

with weights

$$[w_1, w_2, \ldots, w_n],$$

is the quantity calculated by

$$\bar{x} = \frac{\sum_{i=1}^{n} w_i x_i}{\sum_{i=1}^{n} w_i},$$

which means:

$$\bar{x} = \frac{w_1 x_1 + w_2 x_2 + \cdots + w_n x_n}{w_1 + w_2 + \cdots + w_n}.$$

So data elements with a high weight contribute more to the weighted mean than do elements with a low weight. The weights must not be negative. They may be zero, but not all of them (because division by zero is not allowed).

Therefore, one of ordinary skill in the art would readily go to finding the parameters comprising a glucose profile and would put them together in a simple linear combination using weighting factors to arrive at a weighted average value of a glucose profile to produce a predictable and unobvious result.

In *KSR Int'l v. Teleflex*, the Supreme Court, in rejecting the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, indicated that

> The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other

> market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007).

Applying the KSR standard of obviousness to Easterling, Krutz, Nordhoff, Demirev, and Zeng, we conclude that the combination of limitation a) [multiple mass spectrometers, as taught by Krutz], to [analyze multiple proteins at multiple times as taught by Ref A], with preparative steps taught by Ref C, D, represents a combination of known elements which yield the predictable result of permitting [high throughput analysis of protein samples. The use of multiple linked mass spectrometers as taught by Krutz in this combination would further serve to achieve the predictable result of high throughput analysis, since the more components that are linked in parallel, the larger the number of samples which can be subjected to analysis]. Such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR Int'l* 7, 127 S. Ct. at 1740.

Applying the KSR standard of obviousness to Kalatz et al. and Wyman, Examiner concludes that applying the known equation described in Wyman to the method of Kalatz is applying a known technique to a known method

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 and 53 of copending Application No. 2004/0197846. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim in the instant application is a species of the genus application 2004/0197846. The claims in the genus application use the calculated screening factor to inform an individual with information for disease management without specifying a particular disease. The claim in the instant application uses the calculated screening factor to classify an individual into a particular category or class of disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin, Ph.D./

Primary Examiner, Art Unit 1631